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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,681	11/08/2001	David G. Barkalow	112703-198	4991

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EXAMINER

SHEIKH, HUMERA N

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 07/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/036,681

Applicant(s)

BARKALOW ET AL.

Examiner

Humera N. Sheikh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-19 and 25-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-19 and 25-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION
Status of the Application

Receipt of the Request for Continued Examination (RCE), the Amendment and Applicant's Remarks/Arguments, all filed 05/14/04 is acknowledged.

Claims 16-19 and 25-43 are pending. Claims 16, 19, 25 and 41 have been amended. Claims 1-15 and 20-24 have previously been cancelled. Claims 16-19 and 25-43 are rejected.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-19, 25-39 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers (US Pat. No. 5,433,960).

Meyers teaches an edible film composition comprising edible *film-forming agents* consisting of effective amounts (~5 to ~25%) of celluloses, cellulose derivatives, starches, dextrans, maltodextrins, etc. and *combinations thereof* including at least two materials chosen from carbohydrates (derivatives), celluloses, gums (derivatives), proteins and lipids; *bulk filler agents* (5-95%) and *plasticizers* (~5 to ~15%) wherein the edible film composition also comprises at least one or more active agents located in the edible film, which include *dental agents* (i.e., plaque pH buffers/inhibitors, minerals, antimicrobial agents, microbial inhibitors, phosphates); flavor enhancers, sweeteners, softeners and antioxidants (see reference column 3, line 15 thru col. 14, line 18); (col. 6, line 20 thru col. 11, line 55) and claims.

Meyers teaches that suitable water-soluble film forming agents include, asides from the celluloses and starches, edible polymers, edible plastics, low calorie bulking agents, vegetable gums, such as guar gum, locust bean gum, carrageenan gum, alginates, etc. The preferred water-soluble film forming agents are cellulose derivatives, which include ethyl cellulose, methyl cellulose, hydroxypropyl cellulose and sodium hydroxymethyl cellulose. The film-forming agent can be used in amounts of about 5% to about 25% (col. 6, lines 20-50). The ranges of film-forming agents taught by Meyers are overlapping ranges (instant range – ~10 - ~90%).

Bulk fillers, such as calcium carbonate, magnesium carbonate, talc and dicalcium phosphate are disclosed in amounts of between 5-95% at col. 9, lines 14-22.

According to Meyers, plasticizers are added to improve the flexibility of the film. Plasticizers mentioned herein include glycerin, polyethylene glycol (PEG), polyols and hydrogenated starch hydrolysates. The plasticizer may be contained in amounts of about 0.5-15% (instant range - <20%) (col. 8, line 7 thru col. 10, line 30).

Additionally, at least one or more active agents are included in the edible film forming composition, as delineated above.

Claim 40 is rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers (US Pat. No. 5,433,960) in view of Zerbe et al. (US Pat. No. 5,948,430).

Meyers, as discussed above, teaches an edible film composition comprising edible *film-forming agents* consisting of effective amounts (~5 to ~25%) of celluloses, cellulose derivatives, starches, dextrans, maltodextrins, etc. and *combinations thereof* including at least two materials chosen from carbohydrates (derivatives), celluloses, gums (derivatives), proteins and lipids; *bulk filler agents* (5-95%) and *plasticizers* (~5 to ~15%).

Meyers teaches the use of various acids at col. 8, lines 5-11. Meyers is deficient only in the sense that he does not teach an acid from the selective group of claim 40.

Zerbe et al. teach a water-soluble film composition for oral administration comprising film-forming agents, fillers, plasticizers and flavor-enhancing acids, wherein suitable acids include tartaric acid and citric acid (col. 2, line 1 thru col. 3, line 40).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Zerbe et al. within Meyers, because Zerbe et al. explicitly teach a water-soluble film forming composition comprising cosmetically active agents such as flavor-enhancing acids (i.e., tartaric, citric) to impart an enhancement of flavor to the composition and similarly, Meyers teaches an edible water-soluble film forming composition comprising active agents that include flavor enhancers and discloses various acids (i.e., stearic, lauric, palmitic, arachidic, oleic, linoleic and eladic acids). The expected result would be an edible film-forming composition capable of imparting enhancement of flavors and freshness of the mouth, as similarly desired by the Applicant.

Response to Arguments

Applicant's arguments filed 05/14/04 have been fully considered but they are not persuasive.

Applicant specifically argued, "Neither Meyers nor Zerbe teaches or suggests a stand alone edible film as recited in the present claims. Conversely, Meyers discloses a thin coating that is supported by a gum piece surface. Meyers, col. 6, line 56 through col. 7, line 7. Similarly, Zerbe fails to teach or suggest a stand-alone film as the Zerbe film must be supported by a surface allowing an evenly spread coating. Zerbe col. 3, lines 50-60."

Applicant's arguments have been fully considered, but were not found to be persuasive. Meyers teaches an edible film composition comprising edible film-forming agents, bulk filler agents (5-95%) and plasticizers (~5 to ~15%). The prior art teaches a similar composition comprising the same ingredients, which are used for the same field of endeavor as that desired by Applicant. The Applicant's argument that neither Meyers nor Zerbe et al. teach or suggest a 'stand alone edible film' is further not persuasive since the Examiner notes that the instant claims utilize "comprising" claim language, and thus the "comprising" claim language permits the use of additional ingredients besides from those recited in the instant claims. Additional ingredients, in this instance, could be structural support ingredients, such as those taught by Meyers and Zerbe et al. Hence, the instant invention is rendered *prima facie* obvious over the prior art of record.

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Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays from 8:00 A.M. to 4:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns

July 26, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600